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UNITED STATES DEPARTMENT OF COMMERCE **Patent and Trademark Office**

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ART UNIT PAPER NUMBER

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02/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 08/935,629

Applicant(s)

Bates et al.

Examiner

Lyle A. Alexander

Group Art Unit 1743

Responsive to communication(s) filed on Sep 27, 1999	<u> </u>
☐ This action is FINAL .	
☐ Since this application is in condition for allowance except for formal r in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11	
A shortened statutory period for response to this action is set to expire is longer, from the mailing date of this communication. Failure to respon application to become abandoned. (35 U.S.C. § 133). Extensions of tin 37 CFR 1.136(a).	nd within the period for response will cause the
Disposition of Claims	
X Claim(s) 1, 8, and 23-41	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
Claim(s)	is/are allowed.
	is/are rejected.
	is/are objected to.
☐ Claims are	subject to restriction or election requirement.
Application Papers	
☐ See the attached Notice of Draftsperson's Patent Drawing Review	, PTO-948.
☐ The drawing(s) filed on is/are objected to by	the Examiner.
☐ The proposed drawing correction, filed on is	□approved □disapproved.
☐ The specification is objected to by the Examiner.	
\square The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
Acknowledgement is made of a claim for foreign priority under 35	i U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the prio	ority documents have been
received.	
received in Application No. (Series Code/Serial Number)	·
\square received in this national stage application from the Internation	
*Certified copies not received:	
☐ Acknowledgement is made of a claim for domestic priority under	35 U.S.C. § 119(e).
Attachment(s)	
□ Notice of References Cited, PTO-892	
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).	
☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948	
☐ Notice of Informal Patent Application, PTO-152	
SEE OFFICE ACTION ON THE FOLLS	OWING PAGES

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In response to the 9/27/99 appeal brief the final office action mailed 4/28/99 has been vacated in favor of the following new grounds of rejection.

Claim Rejections - 35 USC § 112

1. Claims 25-26, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is confusing as to what is intended by the "space being empty".

- 2. Claim Rejections 35 USC § 102
- 3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4. Claims 1,8 and 23-34 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Senior(USP 5,504,013).

Senior teaches a device with a cartridge/cassette(10) that contains a test strip(16), a window(17) for viewing the results and a well/opening separate from the window(13) for containing the test strip(16). In column 2 lines 30-37 teach the cap "should seal the bibulous sample receiving member from the surrounding environment after sample collection".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Senior.

Senior is silent to a snap fit cap, a method of depositing the sample by pipette and photocopying the results.

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The court decided that optimization of a result effective variable is ordinarily within the skill of the art (see <u>In re Boesch</u> 205 USPQ 215).

Snap fit caps are notoriously well known in the art for the advantage of preventing unintentional removal of a cap. Methods of depositing a sample by means of a pipette are also notoriously well known in the art. Finally, photocopying is notoriously well known in the art to provide a copy of what is present. All of these are results effective variables because they have well known and predictable consequences.

It would have been within the skill of the art to further modify Senior to use a snap fit cap, use a pipette to deposit a sample on the test device and employ a photocopy to record the test results as optimization of result effective variables.

8. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Senior further in view of Owens et al. Or Ullman.

See Senior supra.

Senior is silent to the claimed snap fit relationship for the cover.

Owens et al. teach a urine collection chamber. In column 4 lines 61-63 teach that a snap fit cap may be provided that includes a member that can be pressed into a relief formed in the wall of the chamber. Ullman teaches in column 2 lines 40-44 the use of a snap fit closure means. Such sealing means would be advantageous to prevent unintentional removal of the cap and exposure to a biohazard.

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It would have been within the skill of the art to modify Senior in view of either Owens et al. or Ullman to include a snap fit closure to gain the above advantages.

Allowable Subject Matter

9. Claims 35-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

10. Applicant's arguments filed 11/27/99 were persuasive and resulted in the Office withdrawing the 4/28/99 final Office action in favor of the above Office action. have been fully considered but they are not persuasive.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is (703) 308-3893.

Juli Warden
Supervisory Patent Examiner
Technology Center 1700

LYLE A. ALEXANDER PRIMARY EXAMINER